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February 7, 2006

Wisconsin State Senate
Senate Health Committee
State Capitol
PO Box 7882
Madison, WI 53707-7882

RE: CR 04-095 Testimony – 12/14/05 – Dental Conscious Sedation

Dear Chairperson Carol Roessler and Senate Health Committee Members;

Thank you for the opportunity to testify and participate in the public hearing on CR 04-095 before your committee on Dec. 14, 2005. We benefited by listening to the testimony given concerning the administrative rule that the Wisconsin Dentistry Examining Board (DEB) has been working on for the past three years. The proposed rule covers a wide range of procedures ranging from (1) anxiolysis (medications such as Valium given orally before an appointment or Nitrous Oxide inhaled during an appointment for the purpose of relaxing a patient) to (2) conscious sedation (medications given orally or intravenously to sedate a patient) and including (3) general anesthesia (medications that put a patient to sleep).

The DEB held a public hearing on November 3, 2004 on the original draft of the rule during which time several comments and some objections were raised. In response, a number of changes were made. After listening to the testimony at your hearing and at the hearing before the Assembly Health Committee, it appears that the DEB was successful in addressing most of the areas of concern. The remaining topics of concern appear to be limited to two items within this extensive rule. Your letter to the DEB dated December 16, 2005 requested us to make modifications, specifically in those two areas.

The rule's language regarding **advanced life support training** resulted in an unintended interpretation. New language was formulated to address those concerns and at the January 11, 2006 DEB meeting that change was adopted. Changes were made to DE §§11.05 (1) (b), 11.06(1) (b), and 11.07(1) (b).

Pertaining to **titration**, the DEB, at its January 11, 2006 meeting, revisited the subject and the following summary articulates the process and the rationale used in arriving at the Board's final decision:

Several of the members of the DEB are active in organizations that interact with dental examining boards from other states. Three years ago, it was brought to our attention by board members from other states that the vast majority of state boards had either recently enacted rules or were in the process of writing rules concerning oral conscious sedation. At the same time, several of our members attended an annual meeting of dental state boards that included a day long lecture and discussion on this topic. At that session, proposed regulations and rules were presented. Most of the members of the DEB are members of our respective professional associations and are familiar with articles and position papers regarding the regulation of anesthesia.

The ADA Current Policies as posted on the ADA website includes this language:

> **State Regulation**
> State dental boards have a responsibility to ensure that only dentists who are properly trained, experienced, and currently competent are permitted to use conscious sedation, deep sedation and general anesthesia within their jurisdictions. For this reason, the Association strongly urges state dental boards to regulate dentists' use of these modalities. In addition to identifying educational requirements which are consistent with the Association's Guidelines, state dental boards should evaluate and certify dentists who apply to administer conscious sedation, deep sedation and/or general anesthesia to ensure that the protocol, procedures, facilities, drugs, equipment and personnel utilization meet acceptable standards for safe and appropriate delivery of anesthesia care.

The DEB was also aware of an increase in the numbers of Wisconsin dentists practicing oral conscious sedation. Most of these dentists learned the procedures through a course offered by a relatively new organization (Doctors for Oral Conscious Sedation) which was founded by two general dentists from the east coast who were teaching this technique through a two day course, often given over a weekend. The DEB had received formal complaints about the method of advertising for this service, specifically the use of the term "sleep dentistry." Steps were taken to prohibit those types of unprofessional advertising. In investigating these complaints, individual members of the DEB, assigned to the complaints, reviewed patient records. During the course of that review, cases were discovered where the administration of the medication was not in accordance with professional standards and placed patients at an increased risk.

The DEB studied conscious sedation and titration further and brought an expert, Dr. Joe Best, from Marquette University School of Dentistry to address the Board. He informed the Board that Marquette does not teach titration procedures, that no dental school in the United States teaches titration procedures, and that the dental literature does not support titration protocols for oral conscious sedation. He explained that titration of oral drugs was not effective, difficult to assess proper dosage and placed patients at an increased risk of an adverse outcome.

Representatives from the Doctors for Oral Conscious Sedation (D.O.C.S) organization were invited to speak to the DEB. They explained their protocols concerning titration and provided manuals that participants in the course received. A considerable portion of the course was devoted to marketing and explaining how a dentist using conscious sedation could profit from it. Emphasis was placed on the use of titration to obtain longer appointments and in turn, increased

profits. Since that time, additional states have enacted rules pertaining to conscious sedation. In response to these rules, the D.O.C.S. course currently has less emphasis on marketing/profits in response to these new rules yet still strongly advocates the use of titration.

In addition, the Board looked at the position of the American Dental Association (ADA) concerning titration. This topic is controversial and that controversy is reflected in the language included in this section of the ADA Guidelines for the Use of Conscious Sedation, Deep Sedation and General Anesthesia for Dentists as published on the ADA website:

> Titration – the administration of small incremental doses of a drug until a desired clinical effect is observed. *In accord with this particular definition, the clinical effects of titration of oral medication for the purposes of sedation are unpredictable. Repeated dosing of orally administered sedative agents may result in an alteration of the state of consciousness deeper than the intent of the practitioner. Except in unusual circumstances, the maximum recommended dose of an oral medication should not be exceeded.*

Also on the ADA website is the Primer on "Sedation Dentistry," summarized below:

> Dental boards have expressed concerns with this technique because while the "sedation dentistry" technique may not lead to an unintended deeper level of sedation, unintended consequences can occur through improper dosing. This is because the body absorbs the sedative agents at different rates and additional doses may be prematurely administered to a patient who has not fully absorbed the initial dose thereby compounding the effect. When full sedation is realized, or when the patient reaches peak effect, the patient may then progress into a deeper level of sedation than the dentist intended. This may even occur after the procedure is completed and the patient is at home.
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> Further concerns were expressed given a dentist's education and training directly relating to the anesthesia permit they can legally apply for and maintain. Different levels of sedation privileges require varied levels of necessary advanced education/training and additional requirements for personnel, facilities and equipment. Dentists who do not have the necessary level of education and training may be putting patients at unintended risk. The dentist may have planned (and legally permitted) only to have the patient reach a minimal level of sedation, yet the patient, through repeated doses of oral sedative agents (titration), may progress into a deeper level of sedation. The dentist may not have the necessary education, emergency equipment or training to manage this unintended outcome.
>
> Additional concerns involve the reversal agents for the technique. In a recent article, ADA spokesman on anesthesia, Dr. Joel Weaver explained his concerns with the effectiveness of reversal agents like Flumazenil in the case of an overdose. "While it is true that Flumazenil given intravenously would be effective in reversing much of the sedative effects of Triazolam-like oral sedative drugs in an emergency," Dr. Weaver explained, "there is no published scientific evidence that it is effective when given by any route other than by intravenous injection." The article further explained, "Even then,

there is no data to suggest that it would work fast enough, even if it did eventually work, to rescue a patient from hypoxic brain injury."

Given this background research, our first draft of this proposed rule prohibited titration completely, similar to existing rules in Ohio and Florida. In response to our public hearing, where concerns were raised about the inability of practitioners to maintain satisfactory conscious sedation levels, the DEB revisited the subject of titration.

Further research revealed the following quotes from members of the committee that developed the ADA language on titration:

Dr. Robert Peskin, Chair of the Council on Dental Education and Licensure Committee on Anesthesiology at the time the policy was adopted, explained its purpose. "The concern the ADA had was not with the concept of oral conscious sedation. . . The concern was with the titration of orally administered sedative agents, which could cause a deeper level of sedation than that which was intended by the practitioner."

ADA Committee on Anesthesiology member Dr. Mary George stated, "The guidelines do not prevent anyone from using oral conscious sedation. It does not say you cannot give a second dose - it says titrating is difficult. Titrating in this manner may leave you with a situation where you've gone over the maximum recommended dose, which is something the guidelines say you shouldn't do."

Dr. Joel Weaver, further explained, "It's not to say that dentists shouldn't give oral sedation. The ADA guidelines indicate that the practitioner should avoid the unintended loss of consciousness, and giving multiple oral doses with short time intervals in between has a greater potential to produce that effect."

We wrote new language allowing dentists to give multiple doses at a single appointment allowing for professional judgment and yet protecting the safety of our dental consumers.

The first part of this new language states that the dentist should wait long enough for the first dose of oral medicine to have an affect, before a second dose is given. Based on our review of patients' records, sufficient time was often not allowed for the first dose to take affect before giving more medication. A second, third or even a fourth dose was given before the first dose had been given enough time to have an affect. This illustrates the ADA's concerns of multiple doses given too closely together to achieve the necessary level. This information on the time needed to reach peak plasma level is based on sound research, published, easily obtained, and reviewed by the FDA in the approval process of all drugs.

The second portion of the new language clarified the rule that dentists not exceed the maximum recommended dose of medication in a single day, which is also included in the ADA recommendations. This dosage information is also part of the FDA approval, published and easily obtained.

Critics of this part of the rule wish to include in the language that a dentist should not exceed the

maximum recommended dose *except in unusual circumstances.*

The DEB deliberated and discussed this issue at great length. It is our belief that this rule should not be written with a loophole to include possible extenuating circumstances. While such language might be proper in an association guideline or recommendation, it is not proper for a rule of this sort. If this rule is written with the language, "except in unusual circumstances", then who would define what "unusual circumstances" are and in effect, "unusual circumstances" could apply to any circumstance. This language would so weaken the rule to make it unenforceable. We strongly believe that the existing language allows dentists to administer multiple doses of oral conscious sedation medications in a safe manner utilizing their professional judgment. For the above reasons, we voted at our last meeting to retain the existing language, thereby not including the "except unusual circumstances" provision.

Thank you for your time taken on behalf of this important rule CR 04-095 proposed for the protection and well-being our dental consumers. We welcome any questions or concerns. We understand that pursuant to §227.19 (4) (b) 2, Stats. the period of review for the committee is extended until the 10th working day following receipt by the committees of this modified proposed rule.

Sincerely,

Bruce J. Barrette, D.D.S.
Chair, Wisconsin Dentistry Examining Board

Cc: Wisconsin State Assembly
Assembly Committee on Health
Rep. Underheim, Chair